(2) Describe the circumstances in which each of the five statutory reclassification provisions applies; and

(3) Explain the procedure for reclassification prescribed in the five statutory reclassification provisions.

(b) The criteria for determining the proper class for a device are set forth in §860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type.

(c) Any interested person may submit a petition for reclassification under section 513(e), 514(b), or 515(b). A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(l). The Commissioner may initiate the reclassification of a device classified into class III under sections 513(f) and 520(l) of the act.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992]

§860.123 Reclassification petition: Content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., ''It is requested that — device(s) be reclassified from class III to a class II'';

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of §860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

(8) If the petition is based upon new information under section 513(e), 514(b), or 515(b) of the act, a summary of the new information;

(9) Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition).

(b) Each petition submitted pursuant to this section shall be:

(1) Addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Standards and Regulations (HFZ–84), 5600 Fishers Lane, Rockville, MD 20857;

(2) Marked clearly with the section of the act under which the petition is being submitted, i.e., ''513(e),'' ''513(f),'' ''514(b),'' ''515(b),'' or ''520(l) Petition'';

(3) Bound in a volume or volumes, where necessary; and

(4) Submitted in an original and two copies.

[43 FR 32993, July 28, 1978, as amended at 49 FR 14505, Apr. 12, 1984; 53 FR 11253, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§860.125 Consultation with panels.

(a) When the Commissioner is required to refer a reclassification petition to a classification panel for its recommendation under §860.134, or is required, or chooses, to consult with a panel concerning a reclassification petition, such as under §860.130, §860.132, or §860.136, the Commissioner will distribute a copy of the petition, or its relevant portions, to each panel member and will consult with the panel in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting panel members and, when possible, nonvoting panel members;

(2) Consultation by mail with at least a majority of current voting panel members and, when possible, nonvoting panel members; and

(3) Discussion at a panel meeting.

(b) The method of consultation chosen by the Commissioner will depend upon the importance and complexity of

the subject matter involved and the time available for action. When time and circumstances permit, the Commissioner will consult with a panel through discussion at a panel meeting.

(c) When a petition is submitted under §860.134 for a post-enactment, not substantially equivalent device (''new device''), in consulting with the panel the Commissioner will obtain a recommendation that includes the information described in §860.84(d). In consulting with a panel about a petition submitted under §860.130, §860.132, or §860.136, the Commissioner may or may not obtain a formal recommendation.

§ 860.130 General procedures under section 513(e) of the act.

(a) Section 513(e) of the act applies to reclassification proceedings under the act based upon new information.

(b) A proceeding to reclassify a device under section 513(e) may be initiated:

(1) On the initiative of the Commissioner alone;

(2) On the initiative of the Commissioner in response to a request for change in classification based upon new information, under section 514(b) or 515(b) of the act (see §860.132); or

(3) In response to the petition of an interested person, based upon new information, filed in accordance with §860.123.

(c) By regulation promulgated under this section, the Commissioner may change the classification from class III into:

(1) Class II if the Commissioner determines that special controls in addition to general controls would provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide assurance; or

(2) Class I if the Commissioner determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(d) The rulemaking procedures in §10.40 of this chapter apply to proceedings to reclassify a device under section 513(e), except that the Commissioner may secure a recommendation with respect to a proposed reclassification from the classification panel to which the device was last referred. The panel will consider a proposed reclassification submitted to it by the Commissioner in accordance with the consultation procedures of §860.125. Any recommendation submitted to the Commissioner by the panel will be published in the FEDERAL REGISTER when the Commissioner promulgates a regulation under this section.

(e) Within 180 days after the filing of a petition for reclassification under this section, the Commissioner, by order published in the FEDERAL REGISTER, will either deny the petition or give notice of his intent to initiate a change in the classification of the device.

(f) If a device is reclassified under this section, the regulation effecting the reclassification may revoke any special control or premarket approval requirement that previously applied to the device but that is no longer applicable because of the change in classification.

(g) A regulation under this section changing the classification of a device from class III to class II may provide that such classification will not take effect until the effective date of a special control for the device established under section 514 of the act.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992]

§ 860.132 Procedures when the Commissioner initiates a performance standard or premarket approval proceeding under section 514(b) or 515(b) of the act.

(a) Sections 514(b) and 515(b) of the act require the Commissioner to provide, by notice in the FEDERAL REGISTER, an opportunity for interested parties to request a change in the classification of a device based upon new information relevant to its classification when the Commissioner initiates a proceeding either to develop a performance standard for the device if in class II, or to promulgate a regulation requiring premarket approval for the device if in class III. In either case, if the Commissioner agrees that the new information warrants a change in classification, the Commissioner will publish in the FEDERAL REGISTER notice of the Commissioner's intent to initiate a

proceeding under section 513(e) of the act and §860.130 to effect such a change.

(b) The procedures for effecting a change in classification under sections 514(b) and 515(b) of the act are as follows:

(1) Within 15 days after publication of the Commissioner's notice referred to in paragraph (a) of this section, an interested person files a petition for reclassification in accordance with §860.123.

(2) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with §860.125.

(3) Within 60 days after publication of the notice referred to in paragraph (a) of this section, the Commissioner, by order published in the FEDERAL REGISTER, either denies the petition or gives notice of his intent to initiate a change in classification in accordance with §860.130.

§860.134 Procedures for "new devices" under section 513(f) of the act and reclassification of certain devices.

(a) Section 513(f)(2) of the act applies to proceedings for reclassification of a device currently in class III by operation of section 513(f)(1) of the act. This category includes any device that is to be first introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, unless:

(1) It is substantially equivalent to another device that was in commercial distribution before that date and had not been regulated before that date as a new drug; or

(2) It is substantially equivalent to another device that was not in commercial distribution before such date but which has been classified into class I or class II; or

(3) The Commissioner has classified the device into class I or class II in response to a petition for reclassification under this section.

The Commissioner determines whether a device is ''substantially equivalent'' for purposes of the application of this section. If a manufacturer or importer believes that a device is not ''substantially equivalent'' but that it should not be in class III under the criteria in §860.3(c), the manufacturer or importer may petition for reclassification under this section. A manufacturer or importer who believes that a device is ''substantially equivalent'' and wishes to proceed to market the device shall submit a premarket notification in accordance with Part 807 of this chapter. After considering a premarket notification, the Commissioner will determine whether the device is ''substantially equivalent'' and will notify the manufacturer or importer of such determination in accordance with Part 807 of this chapter.

(b) The procedures for effecting reclassification under section 513(f) of the act are as follows:

(1) The manufacturer or importer of the device petitions for reclassification of the device in accordance with §860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it and allows the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) After determining that the petition contains no deficiencies precluding a decision on it, the Commissioner may for good cause shown refer the petition to the appropriate classification panel for its review and recommendation whether to approve or deny the petition.

(4) Within 90 days after the date the petition is referred to the panel, following the review procedures set forth in §860.84(c) for the original classification of an ''old'' device, the panel submits to the Commissioner its recommendation containing the information set forth in §860.84(d). A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel, if appropriate, and developed a proposed reclassification order. Preliminary panel recommendations are filed in the Dockets Management Branch upon receipt and are available to the public upon request.

(5) The panel recommendation is published in the FEDERAL REGISTER as

soon as practicable and interested persons are provided an opportunity to comment on the recommendation.

(6) Within 90 days after the panel's recommendation is received (and no more than 210 days after the date the petition was filed), the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. If the Commissioner approves the petition, the order will classify the device into class I or class II in accordance with the criteria set forth in §860.3(c) and subject to the applicable requirements of §860.93, relating to the classification of implants, life-supporting or life-sustaining devices, and §860.95, relating to exemptions from certain requirements of the act.

(7) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992]

§860.136 Procedures for transitional products under section 520(l) of the act.

(a) Section 520(l)(2) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section 520(l)(1) of the act. This section applies only to devices that the Food and Drug Administration regarded as ''new drugs'' before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(l) are as follows:

(1) The manufacturer or importer of the device files a petition for reclassification of the device in accordance with §860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it, allowing the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) The Commissioner provides the petitioner an opportunity for a regulatory hearing conducted in accordance with Part 16 of this chapter.

(4) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with §860.125.

(5) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in §860.3(c).

(6) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT

Subpart A—General

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AUTHORITY: Secs. 501, 502, 513, 514, 530–542, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374); secs. 351, 361 of the Public Health Service Act (42 U.S.C. 262, 264).

SOURCE: 45 FR 7484, Feb. 1, 1980, unless otherwise noted.

Subpart A—General

§861.1 Purpose and scope.

(a) This part implements section 514 of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the

establishment, amendment, and revocation of performance standards applicable to devices intended for human use.

(b) The Food and Drug Administration may determine that a performance standard, as described under special controls for class II devices in §860.7(b) of this chapter, is necessary to provide reasonable assurance of the safety and effectiveness of the device. Performance standards may be established for:

(1) A class II device;

(2) A class III device which, upon the effective date of the standard, is reclassified into class II; and

(3) A class III device, as a condition to premarket approval under section 515 of the act, to reduce or eliminate a risk or risks associated with such device.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[45 FR 7484, Feb. 1, 1980, as amended at 45 FR 23686, Apr. 8, 1980; 57 FR 58404, Dec. 10, 1992]

§861.5 Statement of policy.

In carrying out its duties under this section, the Food and Drug Administration will, to the maximum extent practical:

(a) Use personnel, facilities, and other technical support available in other Federal agencies;

(b) Consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(c) Invite participation, through conferences, workshops, or other means, by representatives of scientific, professional, industry, or consumer organizations who can make a significant contribution.

§861.7 Contents of standards.

Any performance standard established under this part will include such provisions as the Food and Drug Administration determines are necessary to provide reasonable assurance of the safety and effectiveness of the device or devices for which it is established. Where necessary to provide such assurance, a standard will address (but need not be limited to):

(a) Performance characteristics of the device;

(b) The design, construction, components, ingredients, and properties of the device, and its compatibility with power systems and connections to such systems;

(c) The manufacturing processes and quality control procedures applicable to the device;

(d) Testing of the device on either a sample or a 100-percent basis by the manufacturer, or, if it is determined that no other more practical means are available to the Food and Drug Administration to assure the conformity of the device to the standard, providing for testing by the Food and Drug Administration or a third person to ensure that the device conforms to the standard;

(e) The publication of the results of each test or of certain tests of the device to show that the device conforms to the portions of the standard for which the test or tests were required;

(f) Manufacturers' certification to purchasers or to the Food and Drug Administration that the device conforms to the applicable performance standard;

(g) Restrictions on the sale and distribution of the device, but only to the extent authorized under section 520(e) of the act;

(h) The use, and the form and content, of labeling for the proper installation, maintenance, operation, and use of the device. Among the provisions that may be required in the labeling are warnings; storage and transportation information; expiration dates; the date and place of manufacture; the results that may be expected if the device is used properly; the ranges of accuracy of diagnostic information; instructions regarding the proper care of, and the proper components, accessories, or other equipment to be used with the device; and statements concerning the appropriate patient population, for example, a statement that the device is considered safe and effective only when used by, or in the treatment of, a patient who has been tested by particular designated procedures

and found to have an illness or condition for which use of the device is indicated by a person skilled in the use of the device.

Subpart B—Procedures for Performance Standards Development and Publication

§ 861.20 Summary of standards development process.

The procedure by which a performance standard for a device may be established, amended, or revoked is as follows:

(a) The Food and Drug Administration (FDA) will publish in the FEDERAL REGISTER a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(1) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device will:

(i) Set forth a finding, with supporting justification, that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device;

(ii) Set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate;

(iii) Invite interested persons to submit to the Food and Drug Administration, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to § 860.132 of this chapter, based on new information relevant to the classification; and

(iv) Invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Commissioner of Food and Drugs.

(2) A notice of proposed rulemaking for the revocation of a performance standard will set forth a finding, with supporting justification, that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(b) A notice under this section will provide for a comment period of not less than 60 days.

(c) If, after publication of a notice under paragraph (a) of this section, FDA receives a request to change the classification of the device, FDA will, within 60 days of the publication of the notice and after consultation with the appropriate panel under § 860.125 of this chapter, either deny the request or give notice of its intent to initiate a change in the classification under § 860.130.

(d) If FDA initiates a rulemaking proceeding under paragraph (a) of this section, FDA will:

(1) Complete the proceeding and establish the performance standard for the device in accordance with this part and § 10.40 of this chapter; or

(2) Terminate the proceeding by publishing in the FEDERAL REGISTER a notice announcing such termination and the reasons therefor and, unless the proceeding is terminated because the device is a banned device, initiate a proceeding in accordance with section 513(e) of the act to reclassify the device; or

(3) Take other appropriate action.

[57 FR 58404, Dec. 10, 1992]

§ 861.24 Existing standard as a proposed standard.

(a) The Food and Drug Administration may accept an existing standard or a proposed or draft standard if it includes:

(1) A description of the procedures used to develop the standard and a list of the persons and organizations that participated in its development, to the extent that such information is available or reasonably obtainable;

(2) An identification of the specific portions of the existing standard that the person submitting the standard believes are appropriate for adoption as, or inclusion in, the proposed standard; and

(3) A summary of the test data, or, if requested by the Food and Drug Administration, all such data or other information supporting the specific portions of the standard identified by the person submitting the standard.

(b) The Food and Drug Administration will publish a notice in the FEDERAL REGISTER stating either that it has accepted, or accepted with modification, as a proposed standard, an existing standard or one that has been

developed, or that an existing standard is not acceptable, together with the reasons therefor.

[45 FR 7484, Feb. 1, 1980, as amended at 57 FR 58405, Dec. 10, 1992]

§861.30 Development of standards.

The Food and Drug Administration (FDA), while engaged in the development of a proposed standard under this section will:

(a) Support its proposed performance standard by such test data or other documents or materials as may reasonably be required;

(b) Provide interested persons an opportunity to participate in the development of the standard by accepting comments and, where appropriate, holding public meetings on issues relating to development of the standard. Notice of the opportunity to participate in the development of the standard will be furnished in a manner reasonably calculated to reach the majority of persons interested in the development of the standard. This requirement shall be satisfied by publishing such a notice in the FEDERAL REGISTER. Whenever it is appropriate, FDA will use the FEDERAL REGISTER to make announcements about the standard development process of standard developers other than Federal agencies.

(c) Maintain records disclosing the course of development of the proposed standard, the comments and other information submitted by a person in connection with such development (including comments and information regarding the need for a standard), and such other information as may be required to evaluate the standard.

[45 FR 7484, Feb. 1, 1980, as amended at 57 FR 58405, Dec. 10, 1992]

§861.34 Amendment or revocation of a standard.

(a) The Food and Drug Administration will provide for periodic evaluation of performance standards to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(b) The Food and Drug Administration may, on its own initiative or upon petition of an interested party, amend or revoke by regulation a standard established under this part.

(c) Any petition to amend or revoke a standard shall:

(1) Identify the specific device and standard for which the amendment or revocation is sought; and

(2) Be submitted in accordance with the requirements of §10.30.

(d) Proceedings to amend or revoke a performance standard shall be conducted in accordance with the rulemaking procedures of §10.40. In addition, a notice of proposed rulemaking to amend or revoke a standard shall set forth proposed findings with respect to the degree of risk or illness to be eliminated or reduced and the benefit the public will derive from the proposed amendment or revocation.

§861.36 Effective dates.

(a) A regulation establishing, amending, or revoking a performance standard will set forth the date upon which it will take effect. To the extent practical, consistent with the public health and safety, such effective date will be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade.

(b) Except as provided in paragraph (c) of this section, no regulation establishing, amending, or revoking a standard may take effect before 1 year after the date of its publication unless:

(1) The Food and Drug Administration determines that an earlier effective date is necessary to protect the public health and safety; or

(2) The standard has been established for a device that, by the effective date of the standard, has been reclassified from class III to class II.

(c) The Food and Drug Administration may declare a proposed regulation amending a standard effective on publication in the FEDERAL REGISTER if it determines that making the regulation so effective is in the public interest. A proposed amendment of a performance standard made effective upon publication may not prohibit the introduction or delivery for introduction into interstate commerce of a device that conforms to the standard without the change or changes provided in the proposed amendment until the effective

date of any final action on the proposal.

[45 FR 7484, Feb. 1, 1980, as amended at 57 FR 58405, Dec. 10, 1992]

§ 861.38 Standards advisory committees.

(a) The Food and Drug Administration will establish advisory committees to which proposed regulations may be referred, and these committees shall consider such referrals in accordance with this section and Part 14 of this chapter. Such advisory committees, which may not be classification panels, shall be considered ad hoc advisory committees. Their members shall be selected in accordance with §§ 14.82 and 14.84, except that no member may be a regular full-time FDA employee. Each advisory committee established under this section shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry.

(b) A proposed regulation to establish, amend, or revoke a performance standard shall be referred to an advisory committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment if:

(1) The Food and Drug Administration determines that such referral is necessary or appropriate under the circumstances; or

(2) Requested by an interested person, in the form of a citizen petition in accordance with § 10.30 of this chapter, which is made within the period provided for comment on the proposed regulation and which demonstrates good cause for referral.

(c) When a proposed regulation is referred to an advisory committee, the Food and Drug Administration will furnish the committee with the data and information upon which the proposed regulation is based. After independently reviewing the materials furnished by the Food and Drug Administration and any other available data and information, the advisory committee shall, within 60 days of the referral, submit a report and recommendation on the proposed regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of the report and recommendation will be publicly displayed in the office of the Dockets Management Branch, Food and Drug Administration.

(d) Where appropriate, each proposed regulation establishing a standard published in the FEDERAL REGISTER will include a call for nominations to the advisory committee for that particular standard.

[45 FR 7484, Feb. 1, 1980, as amended at 57 FR 58405, Dec. 10, 1992]

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

Subpart A—General Provisions

Sec.

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862.1160 Bicarbonate/carbon dioxide test system.
862.1165 Catecholamines (total) test system.
862.1170 Chloride test system.
862.1175 Cholesterol (total) test system.
862.1177 Cholylglycine test system.
862.1180 Chymotrypsin test system.
862.1185 Compound S (11-deoxycortisol) test system.
862.1187 Conjugated sulfolithocholic acid (SLCG) test system.
862.1190 Copper test system.
862.1195 Corticoids test system.
862.1200 Corticosterone test system.
862.1205 Cortisol (hydrocortisone and hydroxycorticosterone) test system.
862.1210 Creatine test system.
862.1215 Creatine phosphokinase/creatine kinase or isoenzymes test system.
862.1225 Creatinine test system.
862.1230 Cyclic AMP test system.
862.1240 Cystine test system.
862.1245 Dehydroepiandrosterone (free and sulfate) test system.
862.1250 Desoxycorticosterone test system.
862.1255 2,3-Diphosphoglyceric acid test system.
862.1260 Estradiol test system.
862.1265 Estriol test system.
862.1270 Estrogens (total, in pregnancy) test system.
862.1275 Estrogens (total, nonpregnancy) test system.
862.1280 Estrone test system.
862.1285 Etiocholanolone test system.
862.1290 Fatty acids test system.
862.1295 Folic acid test system.
862.1300 Follicle-stimulating hormone test system.
862.1305 Formiminoglutamic acid (FIGLU) test system.
862.1310 Galactose test system.
862.1315 Galactose-1-phosphate uridyl transferase test system.
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862.1325 Gastrin test system.
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862.1340 Urinary glucose (nonquantitative) test system.
862.1345 Glucose test system.
862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.
862.1365 Glutathione test system.
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862.1375 Histidine test system.
862.1377 Urinary homocystine (nonquantitative) test system.
862.1380 Hydroxybutyric dehydrogenase test system.
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862.1390 5-Hydroxyindole acetic acid/serotonin test system.
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862.1450 Lactic acid test system.
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862.1460 Leucine aminopeptidase test system.
862.1465 Lipase test system.
862.1470 Lipid (total) test system.
862.1475 Lipoprotein test system.
862.1485 Luteinizing hormone test system.
862.1490 Lysozyme (muramidase) test system.
862.1495 Magnesium test system.
862.1500 Malic dehydrogenase test system.
862.1505 Mucopolysaccharides (nonquantitative) test system.
862.1509 Methylmalonic acid (nonquantitative) test system.
862.1510 Nitrite (nonquantitative) test system.
862.1515 Nitrogen (amino-nitrogen) test system.
862.1520 5′-Nucleotidase test system.
862.1530 Plasma oncometry test system.
862.1535 Ornithine carbamyl transferase test system.
862.1540 Osmolality test system.
862.1542 Oxalate test system.
862.1545 Parathyroid hormone test system.
862.1550 Urinary pH (nonquantitative) test system.
862.1555 Phenylalanine test system.
862.1560 Urinary phenylketones (nonquantitative) test system.
862.1565 6-Phosphogluconate dehydrogenase test system.
862.1570 Phosphohexose isomerase test system.
862.1575 Phospholipid test system.
862.1580 Phosphorus (inorganic) test system.
862.1585 Human placental lactogen test system.
862.1590 Porphobilinogen test system.
862.1595 Porphyrins test system.
862.1600 Potassium test system.
862.1605 Pregnanediol test system.
862.1610 Pregnanetriol test system.

862.1615 Pregnenolone test system.
862.1620 Progesterone test system.
862.1625 Prolactin (lactogen) test system.
862.1630 Protein (fractionation) test system.
862.1635 Total protein test system.
862.1640 Protein-bound iodine test system.
862.1645 Urinary protein or albumin (nonquantitative) test system.
862.1650 Pyruvate kinase test system.
862.1655 Pyruvic acid test system.
862.1660 Quality control material (assayed and unassayed).
862.1665 Sodium test system.
862.1670 Sorbitol dehydrogenase test system.
862.1675 Blood specimen collection device.
862.1680 Testosterone test system.
862.1685 Thyroxine-binding globulin test system.
862.1690 Thyroid-stimulating hormone test system.
862.1695 Free thyroxine test system.
862.1700 Total thyroxine test system.
862.1705 Triglyceride test system.
862.1710 Total triiodothyronine test system.
862.1715 Triiodothyronine uptake test system.
862.1720 Triose phosphate isomerase test system.
862.1725 Trypsin test system.
862.1730 Free tyrosine test system.
862.1770 Urea nitrogen test system.
862.1775 Uric acid test system.
862.1780 Urinary calculi (stones) test system.
862.1785 Urinary urobilinogen (nonquantitative) test system.
862.1790 Uroporphyrin test system.
862.1795 Vanilmandelic acid test system.
862.1805 Vitamin A test system.
862.1810 Vitamin B_{12} test system.
862.1815 Vitamin E test system.
862.1820 Xylose test system.

Subpart C—Clinical Laboratory Instruments

862.2050 General purpose laboratory equipment labeled or promoted for a specific medical use.
862.2100 Calculator/data processing module for clinical use.
862.2140 Centrifugal chemistry analyzer for clinical use.
862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.
862.2160 Discrete photometric chemistry analyzer for clinical use.
862.2170 Micro chemistry analyzer for clinical use.
862.2230 Chromatographic separation material for clinical use.
862.2250 Gas liquid chromatography system for clinical use.
862.2260 High pressure liquid chromatography system for clinical use.
862.2270 Thin-layer chromatography system for clinical use.
862.2300 Colorimeter, photometer, or spectrophotometer for clinical use.
862.2310 Clinical sample concentrator.
862.2320 Beta or gamma counter for clinical use.
862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.
862.2485 Electrophoresis apparatus for clinical use.
862.2500 Enzyme analyzer for clinical use.
862.2540 Flame emission photometer for clinical use.
862.2560 Fluorometer for clinical use.
862.2680 Microtitrator for clinical use.
862.2700 Nephelometer for clinical use.
862.2720 Plasma oncometer for clinical use.
862.2730 Osmometer for clinical use.
862.2750 Pipetting and diluting system for clinical use.
862.2800 Refractometer for clinical use.
862.2850 Atomic absorption spectrophotometer for clinical use.
862.2860 Mass spectrometer for clinical use.
862.2900 Automated urinalysis system.
862.2920 Plasma viscometer for clinical use.

Subpart D—Clinical Toxicology Test Systems

862.3030 Acetaminophen test system.
862.3035 Amikacin test system.
862.3040 Alcohol test system.
862.3050 Breath-alcohol test system.
862.3100 Amphetamine test system.
862.3110 Antimony test system.
862.3120 Arsenic test system.
862.3150 Barbiturate test system.
862.3170 Benzodiazepine test system.
862.3200 Clinical toxicology calibrator.
862.3220 Carbon monoxide test system.
862.3240 Cholinesterase test system.
862.3250 Cocaine and cocaine metabolite test system.
862.3270 Codeine test system.
862.3280 Clinical toxicology control material.
862.3300 Digitoxin test system.
862.3320 Digoxin test system.
862.3350 Diphenylhydantoin test system.
862.3380 Ethosuximide test system.
862.3450 Gentamicin test system.
862.3520 Kanamycin test system.
862.3550 Lead test system.
862.3555 Lidocaine test system.
862.3560 Lithium test system.
862.3580 Lysergic acid diethylamide (LSD) test system.
862.3600 Mercury test system.
862.3610 Methamphetamine test system.
862.3620 Methadone test system.
862.3630 Methaqualone test system.
862.3640 Morphine test system.
862.3645 Neuroleptic drugs radioreceptor assay test system.
862.3650 Opiate test system.
862.3660 Phenobarbital test system.

862.3670 Phenothiazine test system.
862.3680 Primidone test system.
862.3700 Propoxyphene test system.
862.3750 Quinine test system.
862.3830 Salicylate test system.
862.3850 Sulfonamide test system.
862.3870 Cannabinoid test system.
862.3880 Theophylline test system.
862.3900 Tobramycin test system.
862.3910 Tricyclic antidepressant drugs test system.
862.3950 Vancomycin test system.

AUTHORITY: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

SOURCE: 52 FR 16122, May 1, 1987, unless otherwise noted.

Subpart A—General Provisions

§862.1 Scope.

(a) This part sets forth the classification of clinical chemistry and clinical toxicology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required in §807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§862.2 Regulation of calibrators.

Many devices classified in this part are intended to be used with a calibrator. A calibrator has a reference value assigned to it which serves as the basis by which test results of patients are derived or calculated. The calibrator for a device may be (a) manufactured and distributed separately from the device with which it is intended to be used, (b) manufactured and distributed as one of several device components, such as in a kit of reagents, or (c) built-in as an integral part of the device. Because of the central role that a calibrator plays in the measurement process and the critical effect calibrators have on accuracy of test results, elsewhere in this part, all three of these types of calibrators (§§862.1150 and 862.3200 of this part) are classified into class II, notwithstanding the classification of the device with which it is intended to be used. Thus, a device and its calibrator may have different classifications, even if the calibrator is built into the device.

§862.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the

device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a ''new'' device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

§ 862.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

[53 FR 21448, June 8, 1988]

Subpart B—Clinical Chemistry Test Systems

§ 862.1020 Acid phosphatase (total or prostatic) test system.

(a) *Identification.* An acid phosphatase (total or prostatic) test system is a device intended to measure the activity of the acid phosphatase enzyme in plasma and serum.

(b) *Classification.* Class II.

§ 862.1025 Adrenocorticotropic hormone (ACTH) test system.

(a) *Identification.* An adrenocorticotropic hormone (ACTH) test system is a device intended to measure adrenocorticotropic hormone in plasma and serum. ACTH measurements are used in the differential diagnosis and treatment of certain disorders of the adrenal glands such as Cushing's syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.

(b) *Classification.* Class II.

§ 862.1030 Alanine amino transferase (ALT/SGPT) test system.

(a) *Identification.* An alanine amino transferase (ALT/SGPT) test system is a device intended to measure the activity of the enzyme alanine amino transferase (ALT) (also known as a serum glutamic pyruvic transaminase or SGPT) in serum and plasma. Alanine amino transferase measurements are

used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.

(b) *Classification.* Class I.

§ 862.1035 Albumin test system.

(a) *Identification.* An albumin test system is a device intended to measure the albumin concentration in serum and plasma. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

(b) *Classification.* Class II.

§ 862.1040 Aldolase test system.

(a) *Identification.* An aldolase test system is a device intended to measure the activity of the enzyme aldolase in serum or plasma. Aldolase measurements are used in the diagnosis and treatment of the early stages of acute hepatitis and for certain muscle diseases such as progressive Duchenne-type muscular dystrophy.

(b) *Classification.* Class I.

§ 862.1045 Aldosterone test system.

(a) *Identification.* An aldosterone test system is a device intended to measure the hormone aldosterone in serum and urine. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by the excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte imbalance.

(b) *Classification.* Class II.

§ 862.1050 Alkaline phosphatase or isoenzymes test system.

(a) *Identification.* An alkaline phosphatase or isoenzymes test system is a device intended to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum or plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

(b) *Classification.* Class II.

§ 862.1060 Delta-aminolevulinic acid test system.

(a) *Identification.* A *delta*-aminolevulinic acid test system is a device intended to measure the level of *delta*-aminolevulinic acid (a precursor of porphyrin) in urine. *Delta*-aminolevulinic acid measurements are used in the diagnosis and treatment of lead poisoning and certain porphyrias (diseases affecting the liver, gastrointestinal, and nervous systems that are accompanied by increased urinary excretion of various heme compounds including *delta*-aminolevulinic acid).

(b) *Classification.* Class I.

§ 862.1065 Ammonia test system.

(a) *Identification.* An ammonia test system is a device intended to measure ammonia levels in blood, serum, and plasma, Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.

(b) *Classification.* Class I.

§ 862.1070 Amylase test system.

(a) *Identification.* An amylase test system is a device intended to measure the activity of the enzyme amylase in serum and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

(b) *Classification.* Class II.

§ 862.1075 Androstenedione test system.

(a) *Identification.* An androstenedione test system is a device intended to measure androstenedione (a substance secreted by the testes, ovary, and adrenal glands) in serum. Adrostenedione measurements are used in the diagnosis and treatment of females with excessive levels of androgen (male sex hormone) production.

(b) *Classification.* Class I.

§ 862.1080 Androsterone test system.

(a) *Identification.* An androsterone test system is a device intended to measure the hormone adrosterone in serum, plasma, and urine. Androsterone measurements are used in the diagnosis and treatment of gonadal and adrenal diseases.

(b) *Classification.* Class I.

§ 862.1085 Angiotensin I and renin test system.

(a) *Identification.* An angiotensin I and renin test system is a device intended to measure the level of angiotensin I generated by renin in plasma. Angiotensin I measurements are used in the diagnosis and treatment of certain types of hypertension.

(b) *Classification.* Class II.

§ 862.1090 Angiotensin converting enzyme (A.C.E.) test system.

(a) *Identification.* An angiotensin converting enzyme (A.C.E.) test system is a device intended to measure the activity of angiotensin converting enzyme in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diseases such as sarcoidosis, a disease characterized by the formation of nodules in the lungs, bones, and skin, and Gaucher's disease, a hereditary disorder affecting the spleen.

(b) *Classification.* Class II.

§ 862.1095 Ascorbic acid test system.

(a) *Identification.* An ascorbic acid test system is a device intended to measure the level of ascorbic acid (vitamin C) in plasma, serum, and urine. Ascorbic acid measurements are used in the diagnosis and treatment of ascorbic acid dietary deficiencies.

(b) *Classification.* Class I.

§ 862.1100 Aspartate amino transferase (AST/SGOT) test system.

(a) *Identification.* An aspartate amino transferase (AST/SGOT) test system is a device intended to measure the activity of the enzyme aspartate amino transferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

(b) *Classification.* Class II.

§ 862.1110 Bilirubin (total or direct) test system.

(a) *Identification.* A bilirubin (total or direct) test system is a device intended to measure the levels of bilirubin (total or direct) in plasma or serum. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal distruction of red blood cells, if used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

(b) *Classification.* Class II.

§ 862.1113 Bilirubin (total and unbound) in the neonate test system.

(a) *Identification.* A bilirubin (total and unbound) in the neonate test system is a device intended to measure the levels of bilirubin (total and unbound) in the blood (serum) of newborn infants to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

(b) *Classification.* Class I.

[54 FR 30206, July 19, 1989]

§ 862.1115 Urinary bilirubin and its conjugates (nonquantitative) test system.

(a) *Identification.* A urinary bilirubin and its conjugates (nonquantitative) test system is a device intended to measure the levels of bilirubin conjugates in urine. Measurements of urinary bilirubin and its conjugates (nonquantitative) are used in the diagnosis and treatment of certain liver diseases.

(b) *Classification.* Class I.

§ 862.1120 Blood gases ($P_{CO}2$, P_O2) and blood pH test system.

(a) *Identification.* A blood gases ($P_{CO}2$, P_O2) and blood pH test system is a device intended to measure certain gases in blood, serum, plasma or pH of blood, serum, and plasma. Measurements of blood gases ($P_{CO}2$, P_O2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

(b) *Classification.* Class II.

§ 862.1130 Blood volume test system.

(a) *Identification.* A blood volume test system is a device intended to measure the circulating blood volume. Blood volume measurements are used in the diagnosis and treatment of shock, hemorrhage, and polycythemia vera (a disease characterized by an absolute increase in erythrocyte mass and total blood volume).

(b) *Classification.* Class I.

§862.1135 C-peptides of proinsulin test system.

(a) *Identification.* A C-peptides of proinsulin test system is a device intended to measure C-peptides of proinsulin levels in serum, plasma, and urine. Measurements of C-peptides of proinsulin are used in the diagnosis and treatment of patients with abnormal insulin secretion, including diabetes mellitus.

(b) *Classification.* Class I.

§862.1140 Calcitonin test system.

(a) *Identification.* A calcitonin test system is a device intended to measure the thyroid hormone calcitonin (thyrocalcitonin) levels in plasma and serum. Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism (excessive activity of the parathyroid gland).

(b) *Classification.* Class II.

§862.1145 Calcium test system.

(a) *Identification.* A calcium test system is a device intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

(b) *Classification.* Class II.

§862.1150 Calibrator.

(a) *Identification.* A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens. (See also §862.2 in this part.)

(b) *Classification.* Class II.

§862.1155 Human chorionic gonadotropin (HCG) test system.

(a) *Human chorionic gonadotropin (HCG) test system intended for the early detection of pregnancy*—(1) *Identification.* A human chorionic gonadotropin (HCG) test system is a device intended for the early detection of pregnancy is intended to measure HCG, a placental hormone, in plasma or urine.

(2) *Classification.* Class II.

(b) *Human chorionic gonadotropin (HCG) test system intended for any uses other than early detection of pregnancy*—(1) *Identification.* A human chorionic goadotropin (HCG) test system is a device intended for any uses other than early detection of pregnancy (such as an aid in the diagnosis, prognosis, and management of treatment of persons with certain tumors or carcinomas) is intended to measure HCG, a placental hormone, in plasma or urine.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See §862.3.

§862.1160 Bicarbonate/carbon dioxide test system.

(a) *Identification.* A bicarbonate/carbon dioxide test system is a device intended to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

(b) *Classification.* Class II.

§862.1165 Catecholamines (total) test system.

(a) *Identification.* A catecholamines (total) test system is a device intended to determine whether a group of similar compounds (epinephrine, norepinephrine, and dopamine) are present in urine and plasma. Catecholamine determinations are used in the diagnosis and treatment of adrenal medulla and hypertensive disorders, and for catecholamine-secreting tumors (pheochromo-cytoma, neuroblastoma, ganglioneuroma, and retinoblastoma).

(b) *Classification.* Class I.

§862.1170 Chloride test system.

(a) *Identification.* A chloride test system is a device intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and

treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

(b) *Classification.* Class II.

§ 862.1175 Cholesterol (total) test system.

(a) *Identification.* A cholesterol (total) test system is a device intended to measure cholesterol in plasma and serum. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

(b) *Classification.* Class I.

§ 862.1177 Cholylglycine test system.

(a) *Identification.* A cholylglycine test system is a device intended to measure the bile acid cholylglycine in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.

(b) *Classification.* Class II.

§ 862.1180 Chymotrypsin test system.

(a) *Identification.* A chymotrypsin test system is a device intended to measure the activity of the enzyme chymotrypsin in blood and other body fluids and in feces. Chymotrypsin measurements are used in the diagnosis and treatment of pancreatic exocrine insufficiency.

(b) *Classification.* Class I.

§ 862.1185 Compound S (11-deoxycortisol) test system.

(a) *Identification.* A compound S (11-dioxycortisol) test system is a device intended to measure the level of compound S (11-dioxycortisol) in plasma. Compound S is a steroid intermediate in the biosynthesis of the adrenal hormone cortisol. Measurements of compound S are used in the diagnosis and treatment of certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension.

(b) *Classification.* Class I.

§ 862.1187 Conjugated sulfolithocholic acid (SLCG) test system.

(a) *Identification.* A conjugated sulfolithocholic acid (SLCG) test system is a device intended to measure the bile acid SLCG in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.

(b) *Classification.* Class II.

§ 862.1190 Copper test system.

(a) *Identification.* A copper test system is a device intended to measure copper levels in plasma, serum, and urine. Measurements of copper are used in the diagnosis and treatment of anemia, infections, inflammations, and Wilson's disease (a hereditary disease primarily of the liver and nervous system). Test results are also used in monitoring patients with Hodgkin's disease (a disease primarily of the lymph system).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1195 Corticoids test system.

(a) *Identification.* A corticoids test system is a device intended to measure the levels of corticoids (hormones of the adrenal cortex) in serum and p lasma. Measurements of corticoids are used in the diagnosis and treatment of disorders of the cortex of the adrenal glands, especially those associated with hypertension and electrolyte disturbances.

(b) *Classification.* Class I.

§ 862.1200 Corticosterone test system.

(a) *Identification.* A corticosterone test system is a device intended to measure corticosterone (a steroid secreted by the adrenal gland) levels in plasma. Measurements of corticosterone are used in the diagnosis and treatment of adrenal disorders such as adrenal cortex disorders and blocks in cortisol synthesis.

(b) *Classification.* Class I.

§ 862.1205 Cortisol (hydrocortisone and hydroxycorticosterone) test system.

(a) *Identification.* A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device intended to

measure the cortisol hormones secreted by the adrenal gland in plasma and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

(b) *Classification.* Class II.

§862.1210 Creatine test system.

(a) *Identification.* A creatine test system is a device intended to measure creatine (a substance synthesized in the liver and pancreas and found in biological fluids) in plasma, serum, and urine. Measurements of creatine are used in the diagnosis and treatment of muscle diseases and endocrine disorders including hyperthyroidism.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1215 Creatine phosphokinase/creatine kinase or isoenzymes test system.

(a) *Identification.* A creatine phosphokinase/creatine kinase or isoenzymes test system is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma and serum. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

(b) *Classification.* Class II.

§862.1225 Creatinine test system.

(a) *Identification.* A creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

(b) *Classification.* Class II.

§862.1230 Cyclic AMP test system.

(a) *Identification.* A cyclic AMP test system is a device intended to measure the level of adenosine 3′, 5′-monophosphate (cyclic AMP) in plasma, urine, and other body fluids. Cyclic AMP measurements are used in the diagnosis and treatment of endocrine disorders, including hyperparathyroidism (overactivity of the parathyroid gland). Cyclic AMP measurements may also be used in the diagnosis and treatment of Graves' disease (a disorder of the thyroid) and in the differentiation of causes of hypercalcemia (elevated levels of serum calcium.)

(b) *Classification.* Class II.

§862.1240 Cystine test system.

(a) *Identification.* A cystine test system is a device intended to measure the amino acid cystine in urine. Cystine measurements are used in the diagnosis of cystinuria (occurrence of cystine in urine). Patients with cystinuria frequently develop kidney calculi (stones).

(b) *Classification.* Class I.

§862.1245 Dehydroepiandrosterone (free and sulfate) test system.

(a) *Identification.* A dehydroepiandrosterone (free and sulfate) test system is a device intended to measure dehydroepiandrosterone (DHEA) and its sulfate in urine, serum, plasma, and amniotic fluid. Dehydroepiandrosterone measurements are used in the diagnosis and treatment of DHEA-secreting adrenal carcinomas.

(b) *Classification.* Class I.

§862.1250 Desoxycorticosterone test system.

(a) *Identification.* A desoxycorticosterone test system is a device intended to measure desoxycorticosterone (DOC) in plasma and urine. DOC measurements are used in the diagnosis and treatment of patients with hypermineralocorticoidism (excess retention of sodium and loss of potassium) and other disorders of the adrenal gland.

(b) *Classification.* Class I.

§862.1255 2,3-Diphosphoglyceric acid test system.

(a) *Identification.* A 2,3-diphosphoglyceric acid test system is a device intended to measure 2,3-diphosphoglyceric acid (2,3-DPG) in erythrocytes (red blood cells). Measurements of 2,3-diphosphoglyceric acid

are used in the diagnosis and treatment of blood disorders that affect the delivery of oxygen by erythrocytes to tissues and in monitoring the quality of stored blood.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1260 Estradiol test system.

(a) *Identification.* An estradiol test system is a device intended to measure estradiol, an estrogenic steroid, in plasma. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

(b) *Classification.* Class I.

§ 862.1265 Estriol test system.

(a) *Identification.* An estriol test system is a device intended to measure estriol, an estrogenic steroid, in plasma, serum, and urine of pregnant females. Estriol measurements are used in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

(b) *Classification.* Class I.

§ 862.1270 Estrogens (total, in pregnancy) test system.

(a) *Identification.* As estrogens (total, in pregnancy) test system is a device intended to measure total estrogens in plasma, serum, and urine during pregnancy. The device primarily measures estrone plus estradiol. Measurements of total estrogens are used to aid in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

(b) *Classification.* Class I.

§ 862.1275 Estrogens (total, nonpregnancy) test system.

(a) *Identification.* As estrogens (total, nonpregnancy) test system is a device intended to measure the level of estrogens (total estrone, estradiol, and estriol) in plasma, serum, and urine of males and nonpregnant females. Measurement of estrogens (total, nonpregnancy) is used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea (absence of menses) differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(b) *Classification.* Class I.

§ 862.1280 Estrone test system.

(a) *Identification.* An estrone test system is a device intended to measure estrone, an estrogenic steroid, in plasma. Estrone measurements are used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea, differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(b) *Classification.* Class I.

§ 862.1285 Etiocholanolone test system.

(a) *Identification.* An etiocholanolone test system is a device intended to measure etiocholanolone in serum and urine. Etiocholanolone is a metabolic product of the hormone testosterone and is excreted in the urine. Etiocholanolone measurements are used in the diagnosis and treatment of disorders of the testes and ovaries.

(b) *Classification.* Class I.

§ 862.1290 Fatty acids test system.

(a) *Identification.* A fatty acids test system is a device intended to measure fatty acids in plasma and serum. Measurements of fatty acids are used in the diagnosis and treatment of various disorders of lipid metabolism.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1295 Folic acid test system.

(a) *Identification.* A folic acid test system is a device intended to measure the vitamin folic acid in plasma and serum. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia, which is characterized by the presence of megaloblasts (an abnormal red blood cell series) in the bone marrow.

(b) *Classification*. Class II.

[52 FR 16122, May 1, 1987; 53 FR 11645, Apr. 8, 1988]

§862.1300 Follicle-stimulating hormone test system.

(a) *Identification*. A follicle-stimulating hormone test system is a device intended to measure follicle-stimulating hormone (FSH) in plasma, serum, and urine. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal disorders.

(b) *Classification*. Class I.

§862.1305 Formiminoglutamic acid (FIGLU) test system.

(a) *Identification*. A formiminoglutamic acid (FIGLU) test system is a device intended to measure formiminolutamic acid in urine. FIGLU measurements obtained by this device are used in the diagnosis of anemias, such as pernicious anemia and congenital hemolytic anemia.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1310 Galactose test system.

(a) *Identification*. A galactose test system is a device intended to measure galactose in blood and urine. Galactose measurements are used in the diagnosis and treatment of the hereditary disease galactosemia (a disorder of galactose metabolism) in infants.

(b) *Classification*. Class I.

§862.1315 Galactose-1-phosphate uridyl transferase test system.

(a) *Identification*. A galactose-1-phosphate uridyl transferase test system is a device intended to measure the activity of the enzyme galactose-1-phosphate uridyl transferase in erythrocytes (red blood cells). Measurements of galactose-1-phosphate uridyl transferase are used in the diagnosis and treatment of the hereditary disease galactosemia (disorder of galactose metabolism) in infants.

(b) *Classification*. Class II.

§862.1320 Gastric acidity test system.

(a) *Identification*. A gastric acidity test system is a device intended to measure the acidity of gastric fluid. Measurements of gastric acidity are used in the diagnosis and treatment of patients with peptic ulcer, Zollinger-Ellison syndrome (peptic ulcer due to gastrin-secreting tumor of the pancreas), and related gastric disorders.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1325 Gastrin test system.

(a) *Identification*. A gastrin test system is a device intended to measure the hormone gastrin in plasma and serum. Measurements of gastrin are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas).

(b) *Classification*. Class I.

§862.1330 Globulin test system.

(a) *Identification*. A globulin test system is a device intended to measure globulins (proteins) in plasma and serum. Measurements of globulin are used in the diagnosis and treatment of patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

(b) *Classification*. Class I.

§862.1335 Glucagon test system.

(a) *Identification*. A glucagon test system is a device intended to measure the pancreatic hormone glucagon in plasma and serum. Glucagon measurements are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification*. Class I.

§862.1340 Urinary glucose (nonquantitative) test system.

(a) *Identification*. A urinary glucose (nonquantitative) test system is a device intended to measure glucosuria

(glucose in urine). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification.* Class II.

§ 862.1345 Glucose test system.

(a) *Identification.* A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

(b) *Classification.* Class II.

§ 862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.

(a) *Identification.* A gamma-glutamyl transpeptidase and isoenzymes test system is a device intended to measure the activity of the enzyme gamma-glutamyl transpeptidase (GGTP) in plasma and serum. Gamma-glutamyl transpeptidase and isoenzymes measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

(b) *Classification.* Class I.

§ 862.1365 Glutathione test system.

(a) *Identification.* A glutathione test system is a device intended to measure glutathione (the tripeptide of glycine, cysteine, and glutamic acid) in erythrocytes (red blood cells). Glutathione measurements are used in the diagnosis and treatment of certain drug-induced hemolytic (erythrocyte destroying) anemias due to an inherited enzyme deficiency.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1370 Human growth hormone test system.

(a) *Identification.* A human growth hormone test system is a device intended to measure the levels of human growth hormone in plasma. Human growth hormone measurements are used in the diagnosis and treatment of disorders involving the anterior lobe of the pituitary gland.

(b) *Classification.* Class I.

§ 862.1375 Histidine test system.

(a) *Identification.* A histidine test system is a device intended to measure free histidine (an amino acid) in plasma and urine. Histidine measurements are used in the diagnosis and treatment of hereditary histidinemia characterized by excess histidine in the blood and urine often resulting in mental retardation and disordered speech development.

(b) *Classification.* Class I.

§ 862.1377 Urinary homocystine (nonquantitative) test system.

(a) *Identification.* A urinary homocystine (nonquantitative) test system is a device intended to identify homocystine (an analogue of the amino acid cystine) in urine. The identification of urinary homocystine is used in the diagnosis and treatment of homocystinuria (homosystine in urine), a heritable metabolic disorder which may cause mental retardation.

(b) *Classification.* Class II.

§ 862.1380 Hydroxybutyric dehydrogenase test system.

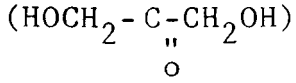
(a) *Identification.* A hydroxybutyric dehydrogenase test system is a device intended to measure the activity of the enzyme alpha-hydroxybutric dehydrogenase (HBD) in plasma or serum. HBD measurements are used in the diagnosis and treatment of myocardial infarction, renal damage (such as rejection of transplants), certain hematological diseases (such as acute leukemias and megaloblastic anemias) and, to a lesser degree, liver disease.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1385 17-Hydroxycorticosteroids (17-ketogenic steroids) test system.

(a) *Identification.* A 17-hydroxycorticosteroids (17-ketogenic steroids) test system is a device intended to measure corticosteroids that possess a dihydroxyacetone



moiety on the steroid nucleus in urine. Corticosteroids with this chemical configuration include cortisol, cortisone 11-desoxycortisol, desoxycorticosterone, and their tetrahydroderivatives. This group of hormones is synthesized by the adrenal gland. Measurements of 17-hydroxycorticosteroids (17-ketogenic steroids) are used in the diagnosis and treatment of various diseases of the adrenal or pituitary glands and gonadal disorders.

(b) *Classification.* Class I.

[52 FR 16122, May. 1, 1987; 52 FR 29468, Aug. 7, 1987]

§862.1390 5-Hydroxyindole acetic acid/serotonin test system.

(a) *Identification.* A 5-hydroxyindole acetic acid/serotonin test system is a device intended to measure 5-hydroxyindole acetic acid/serotonin in urine. Measurements of 5-hydroxyindole acetic acid/serotonin are used in the diagnosis and treatment of carcinoid tumors of endocrine tissue.

(b) *Classification.* Class I.

§862.1395 17-Hydroxyprogesterone test system.

(a) *Identification.* A 17-hydroxyprogesterone test system is a device intended to measure 17-hydroxyprogesterone (a steroid) in plasma and serum. Measurements of 17-hydroxyprogesterone are used in the diagnosis and treatment of various disorders of the adrenal glands or the ovaries.

(b) *Classification.* Class I.

§862.1400 Hydroxyproline test system.

(a) *Identification.* A hydroxyproline test system is a device intended to measure the amino acid hydroxyproline in urine. Hydroxyproline measurements are used in the diagnosis and treatment of various collagen (connective tissue) diseases, bone disease such as Paget's disease, and endocrine disorders such as hyperparathyroidism and hyperthyroidism.

(b) *Classification.* Class I.

§862.1405 Immunoreactive insulin test system.

(a) *Identification.* An immunoreactive insulin test system is a device intended to measure immunoreactive insulin in serum and plasma. Immunoreactive insulin measurements are used in the diagnosis and treatment of various carbohydrate metabolism disorders, including diabetes mellitus, and hypoglycemia.

(b) *Classification.* Class I.

§862.1410 Iron (non-heme) test system.

(a) *Identification.* An iron (non-heme) test system is a device intended to measure iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

(b) *Classification.* Class I.

§862.1415 Iron-binding capacity test system.

(a) *Identification.* An iron-binding capacity test system is a device intended to measure iron-binding capacity in serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

(b) *Classification.* Class I.

§862.1420 Isocitric dehydrogenase test system.

(a) *Identification.* An isocitric dehydrogenase test system is a device intended to measure the activity of the enzyme isocitric dehydrogenase in serum and plasma. Isocitric dehydrogenase measurements are used in the diagnosis and treatment of liver disease such as viral hepatitis, cirrhosis, or acute inflammation of the biliary

tract; pulmonary disease such as pulmonary infarction (local arrest or sudden insufficiency of the blood supply to the lungs), and diseases associated with pregnancy.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1430 17-Ketosteroids test system.

(a) *Identification.* A 17-ketosteroids test system is a device intended to measure 17-ketosteroids in urine. Measurements of 17-ketosteroids are used in the diagnosis and treatment of disorders of the adrenal cortex and gonads and of other endocrine disorders, including hypertension, diabetes, and hypothyroidism.

(b) *Classification.* Class I.

§ 862.1435 Ketones (nonquantitative) test system.

(a) *Identification.* A ketones (nonquantitative) test system is a device intended to identify ketones in urine and other body fluids. Identification of ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets and patients with diabetes.

(b) *Classification.* Class I.

§ 862.1440 Lactate dehydrogenase test system.

(a) *Identification.* A lactate dehydrogenase test system is a device intended to measure the activity of the enzyme lactate dehydrogenase in serum. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys.

(b) *Classification.* Class II.

§ 862.1445 Lactate dehydrogenase isoenzymes test system.

(a) *Identification.* A lactate dehydrogenase isoenzymes test system is a device intended to measure the activity of lactate dehydrogenase isoenzymes (a group of enzymes with similar biological activity) in serum. Measurements of lactate dehydrogenase isoenzymes are used in the diagnosis and treatment of liver diseases, such as viral hepatitis, and myocardial infarction.

(b) *Classification.* Class II.

§ 862.1450 Lactic acid test system.

(a) *Identification.* A lactic acid test system is a device intended to measure lactic acid in whole blood and plasma. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

(b) *Classification.* Class I.

§ 862.1455 Lecithin/sphingomyelin ratio in amniotic fluid test system.

(a) *Identification.* A lecithin/sphingomyelin ratio in amniotic fluid test system is a device intended to measure the lecithin/sphingomyelin ratio in amniotic fluid. Lecithin and sphingomyelin are phospholipids (fats or fat-like substances containing phosphorus). Measurements of the lecithin/sphingomyelin ratio in amniotic fluid are used in evaluating fetal maturity.

(b) *Classification.* Class II.

§ 862.1460 Leucine aminopeptidase test system.

(a) *Identification.* A leucine aminopeptidase test system is a device intended to measure the activity of the enzyme leucine amino-peptidase in serum, plasma, and urine. Leucine aminopeptidase measurements are used in the diagnosis and treatment of liver diseases such as viral hepatitis and obstructive jaundice.

(b) *Classification.* Class I.

§ 862.1465 Lipase test system.

(a) *Identification.* A lipase test system is a device intended to measure the activity of the enzymes lipase in serum. Lipase measurements are used in diagnosis and treatment of diseases of the

pancreas such as acute pancreatitis and obstruction of the pancreatic duct.

(b) *Classification.* Class I.

§862.1470 Lipid (total) test system.

(a) *Identification.* A lipid (total) test system is a device intended to measure total lipids (fats or fat-like substances) in serum and plasma. Lipid (total) measurements are used in the diagnosis and treatment of various diseases involving lipid metabolism and atherosclerosis.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1475 Lipoprotein test system.

(a) *Identification.* A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

(b) *Classification.* Class I.

§862.1485 Luteinizing hormone test system.

(a) *Identification.* A luteinizing hormone test system is a device intended to measure luteinizing hormone in serum and urine. Luteinizing hormone measurements are used in the diagnosis and treatment of gonadal dysfunction.

(b) *Classification.* Class I.

§862.1490 Lysozyme (muramidase) test system.

(a) *Identification.* A lysozyme (muramidase) test system is a device intended to measure the activity of the bacteriolytic enzyme lysozyme (muramidase) in serum, plasma, leukocytes, and urine. Lysozyme measurements are used in the diagnosis and treatment of monocytic leukemia and kidney disease.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1495 Magnesium test system.

(a) *Identification.* A magnesium test system is a device intended to measure magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

(b) *Classification.* Class I.

§862.1500 Malic dehydrogenase test system.

(a) *Identification.* A malic dehydrogenase test system is a device that is intended to measure the activity of the enzyme malic dehydrogenase in serum and plasma. Malic dehydrogenase measurements are used in the diagnosis and treatment of muscle and liver diseases, myocardial infarctions, cancer, and blood disorders such as myelogenous (produced in the bone marrow) leukemia.

(b) *Classification.* Class I.

§862.1505 Mucopolysaccharides (nonquantitative) test system.

(a) *Identification.* A mucopolysaccharides (nonquantitative) test system is a device intended to measure the levels of mucopolysaccharides in urine. Mucopolysaccharide measurements in urine are used in the diagnosis and treatment of various inheritable disorders that affect bone and connective tissues, such as Hurler's, Hunter's, Sanfilippo's, Scheie's Morquio's and Maroteaux-Lamy syndromes.

(b) *Classification.* Class I.

§862.1509 Methylmalonic acid (nonquantitative) test system.

(a) *Identification.* A methylmalonic acid (nonquantitative) test system is a device intended to identify methylmalonic acid in urine. The identification of methylmalonic acid in urine is used in the diagnosis and treatment of methylmalonic aciduria, a heritable metabolic disorder which, if

untreated, may cause mental retardation.

(b) *Classification.* Class II.

§ 862.1510 Nitrite (nonquantitative) test system.

(a) *Identification.* A nitrite (nonquantitative) test system is a device intended to identify nitrite in urine. Nitrite identification is used in the diagnosis and treatment of uninary tract infection of bacterial origin.

(b) *Classification.* Class I.

§ 862.1515 Nitrogen (amino-nitrogen) test system.

(a) *Identification.* A nitrogen (amino-nitrogen) test system is a device intended to measure amino acid nitrogen levels in serum, plasma, and urine. Nitrogen (amino-nitrogen) measurements are used in the diagnosis and treatment of certain forms of severe liver disease and renal disorders.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1520 5′-Nucleotidase test system.

(a) *Identification.* A 5′-nucleotidase test system is a device intended to measure the activity of the enzyme 5′-nucleotidase in serum and plasma. Measurements of 5′-nucleotidase are used in the diagnosis and treatment of liver diseases and in the differentiations between liver and bone diseases in the presence of elevated serum alkaline phosphatase activity.

(b) *Classification.* Class I.

§ 862.1530 Plasma oncometry test system.

(a) *Identification.* A plasma oncometry test system is a device intended to measure plasma oncotic pressure. Plasma oncotic pressure is that portion of the total fluid pressure contributed by proteins and other molecules too large to pass through a specified membrane. Measurements of plasma oncotic pressure are used in the diagnosis and treatment of dehydration and circulatory disorders related to low serum protein levels and increased capillary permeability, such as edema and shock.

(b) *Classification.* Class I.

§ 862.1535 Ornithine carbamyl transferase test system.

(a) *Identification.* An ornithine carbamyl transferase test system is a device intended to measure the activity of the enzyme ornithine carbamyl transferase (OCT) in serum. Ornithine carbamyl transferase measurements are used in the diagnosis and treatment of liver diseases, such as infectious hepatitis, acute cholecystitis (inflammation of the gall bladder), cirrhosis, and liver metastases.

(b) *Classification.* Class I.

§ 862.1540 Osmolality test system.

(a) *Identification.* An osmolality test system is a device intended to measure ionic and nonionic solute concentration in body fluids, such as serum and urine. Osmolality measurement is used as an adjunct to other tests in the evaluation of a variety of diseases, including kidney diseases (e.g., chronic progressive renal failure), diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances.

(b) *Classification.* Class I.

§ 862.1542 Oxalate test system.

(a) *Identification.* An oxalate test system is a device intended to measure the concentration of oxalate in urine. Measurements of oxalate are used to aid in the diagnosis or treatment of urinary stones or certain other metabolic disorders.

(b) *Classification.* Class I.

§ 862.1545 Parathyroid hormone test system.

(a) *Identification.* A parathyroid hormone test system is a device intended to measure the levels of parathyroid hormone in serum and plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

(b) *Classification.* Class II.

§862.1550 Urinary pH (nonquantitative) test system.

(a) *Identification.* A urinary pH (nonquantitative) test system is a device intended to estimate the pH of urine. Estimations of pH are used to evaluate the acidity or alkalinity of urine as it relates to numerous renal and metabolic disorders and in the monitoring of patients with certain diets.

(b) *Classification.* Class I.

§862.1555 Phenylalanine test system.

(a) *Identification.* A phenylalanine test system is a device intended to measure free phenylalanine (an amino acid) in serum, plasma, and urine. Measurements of phenylalanine are used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

(b) *Classification.* Class II.

§862.1560 Urinary phenylketones (nonquantitative) test system.

(a) *Identification.* A urinary phenylketones (nonquantitative) test system is a device intended to identify phenylketones (such as phenylpyruvic acid) in urine. The identification of urinary phenylketones is used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.

(b) *Classification.* Class I.

§862.1565 6-Phosphogluconate dehydrogenase test system.

(a) *Identification.* A 6-phosphogluconate dehydrogenase test system is a device intended to measure the activity of the enzyme 6-phosphogluconate dehydrogenase (6 PGD) in serum and erythrocytes. Measurements of 6-phosphogluconate dehydrogenase are used in the diagnosis and treatment of certain liver diseases (such as hepatitis) and anemias.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1570 Phosphohexose isomerase test system.

(a) *Identification.* A phosphohexose isomerase test system is a device intended to measure the activity of the enzyme phosphohexose isomerase in serum. Measurements of phosphohexose isomerase are used in the diagnosis and treatment of muscle diseases such as muscular dystrophy, liver diseases such as hepatitis or cirrhosis, and metastatic carcinoma.

(b) *Classification.* Class I.

§862.1575 Phospholipid test system.

(a) *Identification.* A phospholipid test system is a device intended to measure phospholipids in serum and plasma. Measurements of phospholipids are used in the diagnosis and treatment of disorders involving lipid (fat) metabolism.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1580 Phosphorus (inorganic) test system.

(a) *Identification.* A phosphorus (inorganic) test system is a device intended to measure inorganic phosphorus in serum, plasma, and urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

(b) *Classification.* Class I.

§862.1585 Human placental lactogen test system.

(a) *Identification.* A human placental lactogen test system is a device intended to measure the hormone human placental lactogen (HPL), (also known as human chorionic somatomammotrophin (HCS)), in maternal serum and maternal plasma. Measurements of human placental lactogen are used in the diagnosis and clinical management of high-risk pregnancies involving fetal distress associated with placental insufficiency. Measurements of HPL are also used in

pregnancies complicated by hypertension, proteinuria, edema, post-maturity, placental insufficiency, or possible miscarriage.

(b) *Classification.* Class II.

§ 862.1590 Porphobilinogen test system.

(a) *Identification.* A porphobilinogen test system is a device intended to measure porphobilinogen (one of the derivatives of hemoglobin which can make the urine a red color) in urine. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrine metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class I.

§ 862.1595 Porphyrins test system.

(a) *Identification.* A porphyrins test system is a device intended to measure porphyrins (compounds formed during the biosynthesis of heme, a constituent of hemoglobin, and related compounds) in urine and feces. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning, porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class I.

§ 862.1600 Potassium test system.

(a) *Identification.* A potassium test system is a device intended to measure potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

(b) *Classification.* Class II.

§ 862.1605 Pregnanediol test system.

(a) *Identification.* A pregnanediol test system is a device intended to measure pregnanediol (a major urinary metabolic product of progesterone) in urine. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

(b) *Classification.* Class I.

§ 862.1610 Pregnanetriol test system.

(a) *Identification.* A pregnanetriol test system is a device intended to measure pregnanetriol (a precursor in the biosynthesis of the adrenal hormone cortisol) in urine. Measurements obtained by this device are used in the diagnosis and treatment of congenital adrenal hyperplasia (congenital enlargement of the adrenal gland).

(b) *Classification.* Class I.

§ 862.1615 Pregnenolone test system.

(a) *Identification.* A pregnenolone test system is a device intended to measure pregnenolone (a precursor in the biosynthesis of the adrenal hormone cortisol and adrenal androgen) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diseases of the adrenal cortex or the gonads.

(b) *Classification.* Class I.

§ 862.1620 Progesterone test system.

(a) *Identification.* A progesterone test system is a device intended to measure progesterone (a female hormone) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.

(b) *Classification.* Class I.

§ 862.1625 Prolactin (lactogen) test system.

(a) *Identification.* A prolactin (lactogen) test system is a device intended to measure the anterior pituitary polypeptide hormone prolactin in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain.

(b) *Classification.* Class I.

§ 862.1630 Protein (fractionation) test system.

(a) *Identification.* A protein (fractionation) test system is a device intended to measure protein fractions in blood, urine, cerebrospinal fluid, and other body fluids. Protein fractionations are used as a aid in recognizing abnormal proteins in body fluids and genetic variants of proteins produced in diseases with tissue destruction.

(b) *Classification*. Class I.

§862.1635 Total protein test system.

(a) *Identification*. A total protein test system is a device intended to measure total protein(s) in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

(b) *Classification*. Class II.

§862.1640 Protein-bound iodine test system.

(a) *Identification*. A protein-bound iodine test system is a device intended to measure protein-bound iodine in serum. Measurements of protein-bound iodine obtained by this device are used in the diagnosis and treatment of thyroid disorders.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1645 Urinary protein or albumin (nonquantitative) test system.

(a) *Identification*. A urinary protein or albumin (nonquantitative) test system is a device intended to identify proteins or albumin in urine. Identification of urinary protein or albumin (nonquantitative) is used in the diagnosis and treatment of disease conditions such as renal or heart diseases or thyroid disorders, which are characterized by proteinuria or albuminuria.

(b) *Classification*. Class I.

§862.1650 Pyruvate kinase test system.

(a) *Identification*. A pyruvate kinase test system is a device intended to measure the activity of the enzyme pyruvate kinase in erythrocytes (red blood cells). Measurements obtained by this device are used in the diagnosis and treatment of various inherited anemias due to pyruvate kinase deficiency or of acute leukemias.

(b) *Classification*. Class I.

§862.1655 Pyruvic acid test system.

(a) *Identification*. A pyruvic acid test system is a device intended to measure pyruvic acid (an intermediate compound in the metabolism of carbohydrate) in plasma. Measurements obtained by this device are used in the evaluation of electrolyte metabolism and in the diagnosis and treatment of acid-base and electrolyte disturbances or anoxia (the reduction of oxygen in body tissues).

(b) *Classification*. Class I.

§862.1660 Quality control material (assayed and unassayed).

(a) *Identification*. A quality control material (assayed and unassayed) for clinical chemistry is a device intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. A quality control material (assayed and unassayed) may be used for proficiency testing in interlaboratory surveys. This generic type of device includes controls (assayed and unassayed) for blood gases, electrolytes, enzymes, multianalytes (all kinds), single (specified) analytes, or urinalysis controls.

(b) *Classification*. Class I.

§862.1665 Sodium test system.

(a) *Identification*. A sodium test system is a device intended to measure sodium in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

(b) *Classification*. Class II.

§862.1670 Sorbitol dehydrogenase test system.

(a) *Identification*. A sorbitol dehydrogenase test system is a device intended to measure the activity of the enzyme sorbitol dehydrogenase in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders such as cirrhosis or acute hepatitis.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1675 Blood specimen collection device.

(a) *Identification.* A blood specimen collection device is a device intended for medical purposes to collect and to handle blood specimens and to separate serum from nonserum (cellular) components prior to further testing. This generic type device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.

(b) *Classification.* Class II.

§ 862.1680 Testosterone test system.

(a) *Identification.* A testosterone test system is a device intended to measure testosterone (a male sex hormone) in serum, plasma, and urine. Measurement of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

(b) *Classification.* Class I.

[52 FR 16122, May 1, 1987; 53 FR 11645, Apr. 8, 1988]

§ 862.1685 Thyroxine-binding globulin test system.

(a) *Identification.* A thyroxine-binding globulin test system is a device intended to measure thyroxine (thyroid)-binding globulin (TBG), a plasma protein which binds thyroxine, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1690 Thyroid stimulating hormone test system.

(a) *Identification.* A thyroid stimulating hormone test system is a device intended to measure thyroid stimulating hormone, also known as thyrotrophin and thyrotrophic hormone, in serum and plasma. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

(b) *Classification.* Class II.

§ 862.1695 Free thyroxine test system.

(a) *Identification.* A free thyroxine test system is a device intended to measure free (not protein bound) thyroxine (thyroid hormone) in serum or plasma. Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1700 Total thyroxine test system.

(a) *Identification.* A total thyroxine test system is a device intended to measure total (free and protein bound) thyroxine (thyroid hormone) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1705 Triglyceride test system.

(a) *Identification.* A triglyceride test system is a device intended to measure triglyceride (neutral fat) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

(b) *Classification.* Class I.

§ 862.1710 Total triiodothyronine test system.

(a) *Identification.* A total triiodothyronine test system is a device intended to measure the hormone triiodothyronine in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases such as hyperthyroidism.

(b) *Classification.* Class II.

§862.1715 Triiodothyronine uptake test system.

(a) *Identification.* A triiodothyronine uptake test system is a device intended to measure the total amount of binding sites available for binding thyroid hormone on the thyroxine-binding proteins, thyroid-binding globulin, thyroxine-binding prealbumin, and albumin of serum and plasma. The device provides an indirect measurement of thyrkoxine levels in serum and plasma. Measurements of triiodothyronine uptake are used in the diagnosis and treatment of thyroid disorders.

(b) *Classification.* Class II.

§862.1720 Triose phosphate isomerase test system.

(a) *Identification.* A triose phosphate isomerase test system is a device intended to measure the activity of the enzyme triose phosphate isomerase in erythrocytes (red blood cells). Triose phosphate isomerase is an enzyme important in glycolysis (the energy-yielding conversion of glucose to lactic acid in various tissues). Measurements obtained by this device are used in the diagnosis and treatment of congenital triose phosphate isomerase enzyme deficiency, which causes a type of hemolytic anemia.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§862.1725 Trypsin test system.

(a) *Identification.* A trypsin test system is a device intended to measure the activity of trypsin (a pancreatic enzyme important in digestion for the breakdown of proteins) in blood and other body fluids and in feces. Measurements obtained by this device are used in the diagnosis and treatment of pancreatic disease.

(b) *Classification.* Class I.

§862.1730 Free tyrosine test system.

(a) *Identification.* A free tyrosine test system is a device intended to measure free tyrosine (an amono acid) in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of diseases such as congenital tyrosinemia (a disease that can cause liver/kidney disorders) and as an adjunct to the measurement of phenylalanine in detecting congenital phenylketonuria (a disease that can cause brain damage).

(b) *Classification.* Class I.

§862.1770 Urea nitrogen test system.

(a) *Identification.* A urea nitrogen test system is a device intended to measure urea nitrogen (an end-product of nitrogen metabolism) in whole blood, serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

(b) *Classification.* Class II.

§862.1775 Uric acid test system.

(a) *Identification.* A uric acid test system is a device intended to measure uric acid in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

(b) *Classification.* Class I.

§862.1780 Urinary calculi (stones) test system.

(a) *Identification.* A urinary calculi (stones) test system is a device intended for the analysis of urinary calculi. Analysis of urinary calculi is used in the diagnosis and treatment of calculi of the urinary tract.

(b) *Classification.* Class I.

§862.1785 Urinary urobilinogen (nonquantitative) test system.

(a) *Identification.* A urinary urobilinogen (nonquantitative) test system is a device intended to detect and estimate urobilinogen (a bile pigment degradation product of red cell hemoglobin) in urine. Estimations obtained by this device are used in the diagnosis and treatment of liver diseases and hemolytic (red cells) disorders.

(b) *Classification.* Class I.

§862.1790 Uroporphyrin test system.

(a) *Identification.* A uroporphyrin test system is a device intended to measure

uroporphyrin in urine. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

(b) *Classification.* Class I.

§ 862.1795 Vanilmandelic acid test system.

(a) *Identification.* A vanilmandelic acid test system is a device intended to measure vanilmandelic acid in urine. Measurements of vanilmandelic acid obtained by this device are used in the diagnosis and treatment of neuroblastoma, pheochromocytoma, and certain hypertensive conditions.

(b) *Classification.* Class I.

§ 862.1805 Vitamin A test system.

(a) *Identification.* A vitamin A test system is a device intended to measure vitamin A in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of vitamin A deficiency conditions, including night blindness, or skin, eye, or intestinal disorders.

(b) *Classification.* Class I.

§ 862.1810 Vitamin B_{12} test system.

(a) *Identification.* A vitamin B_{12} test system is a device intended to measure vitamin B_{12} in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

(b) *Classification.* Class II.

§ 862.1815 Vitamin E test system.

(a) *Identification.* A vitamin E test system is a device intended to measure vitamin E (tocopherol) in serum. Measurements obtained by this device are used in the diagnosis and treatment of infants with vitamin E deficiency syndrome.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1820 Xylose test system.

(a) *Identification.* A xylose test system is a device intended to measure xylose (a sugar) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of gastrointestinal malabsorption syndrome (a group of disorders in which there is subnormal absorption of dietary constituents and thus excessive loss from the body of the nonabsorbed substances).

(b) *Classification.* Class I.

Subpart C—Clinical Laboratory Instruments

§ 862.2050 General purpose laboratory equipment labeled or promoted for a specific medical use.

(a) *Identification.* General purpose laboratory equipment labeled or promoted for a specific medical use is a device that is intended to prepare or examine specimens from the human body and that is labeled or promoted for a specific medical use.

(b) *Classification.* Class I. The device identified in paragraph (a) of this section is exempt from the premarket notification procedures in Subpart E of Part 807 and is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 862.2100 Calculator/data processing module for clinical use.

(a) *Identification.* A calculator/data processing module for clinical use is an electronic device intended to store, retrieve, and process laboratory data.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.2140 Centrifugal chemistry analyzer for clinical use.

(a) *Identification.* A centrifugal chemistry analyzer for clinical use is an automatic device intended to centrifugally mix a sample and a reagent

and spectrophotometrically measure concentrations of the sample constituents. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

(b) *Classification*. Class I.

§862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.

(a) *Identification*. A continuous flow sequential multiple chemistry analyzer for clinical use is a modular analytical instrument intended to simultaneously perform multiple chemical procedures using the principles of automated continuous flow systems. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

(b) *Classification*. Class I.

§862.2160 Discrete photometric chemistry analyzer for clinical use.

(a) *Identification*. A discrete photometric chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes. Different models of the device incorporate various instrumentation such as micro analysis apparatus, double beam, single, or dual channel photometers, and bichromatic 2-wavelength photometers. Some models of the device may include reagent-containing components that may also serve as reaction units.

(b) *Classification*. Class I.

§862.2170 Micro chemistry analyzer for clinical use.

(a) *Identification*. A micro chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. The distinguishing characteristic of the device is that it requires only micro volume samples obtainable from pediatric patients. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

(b) *Classification*. Class I.

§862.2230 Chromatographic separation material for clinical use.

(a) *Identification*. A chromatographic separation material for clinical use is a device accessory (e.g., ion exchange absorbents, ion exchagne resins, and ion papers) intended for use in ion exchange chromatography, a procedure in which a compound is separated from a solution.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 16122, May 1, 1987, as amended at 61 FR 1119, Jan. 16, 1996]

§862.2250 Gas liquid chromatography system for clinical use.

(a) *Identification*. A gas liquid chromatography system for clinical use is a device intended to separate one or more drugs or compounds from a mixture. Each of the constituents in a vaporized mixture of compounds is separated according to its vapor pressure. The device may include accessories such as columns, gases, column supports, and liquid coating.

(b) *Classification*. Class I.

§862.2260 High pressure liquid chromatography system for clinical use.

(a) *Identification*. A high pressure liquid chromatography system for clinical use is a device intended to separate one or more drugs or compounds from a solution by processing the mixture of compounds (solutes) through a column packed with materials of uniform size (stationary phase) under the influence of a high pressure liquid (mobile phase). Separation of the solutes occurs either by absorption, sieving, partition, or selective affinity.

(b) *Classification*. Class I.

§862.2270 Thin-layer chromatography system for clinical use.

(a) *Identification*. A thin-layer chromatography (TLC) system for clinical use is a device intended to separate one or more drugs or compounds from a mixture. The mixture of compounds is absorbed onto a stationary phase or

thin layer of inert material (e.g., cellulose, alumina, etc.) and eluted off by a moving solvent (moving phase) until equilibrium occurs between the two phases.

(b) *Classification.* Class I. Particular components of TLC systems, i.e., the thin-layer chromatography apparatus, TLC atomizer, TLC developing tanks, and TLC ultraviolet light, are exempt from the current good manufacturing practice regulations in Part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 862.2300 Colorimeter, photometer, or spectrophotometer for clinical use.

(a) *Identification.* A colorimeter, a photometer, or a spectrophotometer for clinical use is an instrument intended to measure radiant energy emitted, transmitted, absorbed, or reflected under controlled conditions. The device may include a monochromator to produce light of a specific wavelength.

(b) *Classification.* Class I.

§ 862.2310 Clinical sample concentrator.

(a) *Identification.* A clinical sample concentrator is a device intended to concentrate (by dialysis, evaporation, etc.) serum, urine, cerebrospinal fluid, and other body fluids before the fluids are analyzed.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38899, July 28, 1995]

§ 862.2320 Beta or gamma counter for clinical use.

(a) *Identification.* A beta or gamma counter for clinical use is a device intended to detect and count beta or gamma radiation emitted by clinical samples. Clinical samples are prepared by addition of a radioactive reagent to the sample. These measurements are useful in the diagnosis and treatment of various disorders.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38900, July 28, 1995]

§ 862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.

(a) *Identification.* A densitometer/scanner (integrating, reflectance, thin-layer chromatography, or radiochromatogram) for clinical use is device intended to measure the concentration of a substance on the surface of a film or other support media by either a photocell measurement of the light transmission through a given area of the medium or, in the case of the radiochromatogram scanner, by measurement of the distribution of a specific radio-active element on a radiochromatogram.

(b) *Classification.* Class I.

§ 862.2485 Electrophoresis apparatus for clinical use.

(a) *Identification.* An electrophoresis apparatus for clinical use is a device intended to separate molecules or particles, including plasma proteins, lipoproteins, enzymes, and hemoglobulins on the basis of their net charge in specified buffered media. This device is used in conjunction with certain materials to measure a variety of analytes as an aid in the diagnosis and treatment of certain disorders.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38900, July 28, 1995]

§ 862.2500 Enzyme analyzer for clinical use.

(a) *Identification.* An enzyme analyzer for clinical use is a device intended to measure enzymes in plasma or serum by nonkinetic or kinetic measurement of enzyme-catalyzed reactions. This device is used in conjunction with certain materials to measure a variety of enzymes as an aid in the diagnosis and treatment of certain enzyme-related disorders.

(b) *Classification.* Class I.

§862.2540 Flame emission photometer for clinical use.

(a) *Identification.* A flame emission photometer for clinical use is a device intended to measure the concentration of sodium, potassium, lithium, and other metal ions in body fluids. Abnormal variations in the concentration of these substances in the body are indicative of certain disorders (e.g., electrolyte imbalance and heavy metal intoxication) and are, therefore, useful in diagnosis and treatment of those disorders.

(b) *Classification.* Class I.

§862.2560 Fluorometer for clinical use.

(a) *Identification.* A fluorometer for clinical use is a device intended to measure by fluorescence certain analytes. Fluorescence is the property of certain substances of radiating, when illuminated, a light of a different wavelength. This device is used in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I.

§862.2680 Microtitrator for clinical use.

(a) *Identification.* A microtitrator for clinical use is a device intended for use in micronanalysis to measure the concentration of a substance by reacting it with a measure ''micro'' volume of a known standardized solution.

(b) *Classification.* Class I.

§862.2700 Nephelometer for clinical use.

(a) *Identification.* A nephelometer for clinical use is a device intended to estimate the concentration of particles in a suspension by measuring their light scattering properties (the deflection of light rays by opaque particles in their path). The device is used in conjunction with certain materials to measure the concentration of a variety of analytes.

(b) *Classification.* Class I.

§862.2720 Plasma oncometer for clinical use.

(a) *Identification.* A plasma oncometer for clinical use is a device intended to measure plasma oncotic pressure, which is that portion of the total plasma osmotic pressure contributed by protein and other molecules too large to pass through a specified semipermeable membrane. Because variations in plasma oncotic pressure are indications of certain disorders, measurements of the variations are useful in the diagnosis and treatment of these disorders.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38900, July 28, 1995]

§862.2730 Osmometer for clinical use.

(a) *Identification.* An osmometer for clinical use is a device intended to measure the osmotic pressure of body fluids. Osmotic pressure is the pressure required to prevent the passage of a solution with a lesser solute concentration into a solution with greater solute concentration when the two solutions are separated by a semipermeable membrane. The concentration of a solution affects its osmotic pressure, freezing point, and other physiochemical properties. Osmometers determine osmotic pressure by methods such as the measurement of the freezing point. Measurements obtained by this device are used in the diagnosis and treatment of body fluid disorders.

(b) *Classification.* Class I.

§862.2750 Pipetting and diluting system for clinical use.

(a) *Identification.* A pipetting and diluting system for clinical use is a device intended to provide an accurately measured volume of liquid at a specified temperature for use in certain test procedures. This generic type of device system includes serial, manual, automated, and semi-automated dilutors, pipettors, dispensers, and pipetting stations.

(b) *Classification.* Class I.

§862.2800 Refractometer for clinical use.

(a) *Identification.* A refractometer for clinical use is a device intended to determine the amount of solute in a solution by measuring the index of refraction (the ratio of the velocity of light in a vacuum to the velocity of light in